

WHAT IS CLAIMED IS:

1. A modular robotic system comprising:

a rack and vial storage system for storing racks and vials;

a consumables storage system for storing materials;

5 a robotic arm for transferring vials from a first location to a second location, or for transferring racks from a first location to a second location;

a dispensing, pipetting, or characterization station for dispensing active ingredients, water, or additives to vials to yield a formulation, wherein said robotic arm transfers materials from said consumables storage system to said dispensing, pipetting, or characterization station;

10 a mixing station for mixing formulation to yield mixture; and

a phase stability station for phase analysis of said mixture;

wherein said first location is:

rack and vial storage system,

dispensing, pipetting or characterization station,

15 mixing or homogenizing station, or

phase stability station; and

wherein said second location is:

rack and vial storage system,

dispensing, pipetting or characterization station,

20 mixing station, or

phase stability station.

2. The modular robotic system of claim 1, further comprising:

a flexible robotic arm, wherein said flexible robotic arm transfer racks from robotic arm to a third location upon modular robotic system.

25 3. The modular robotic system of claim 2, further comprising:

a comminution station for grinding solid particles, wherein said solid particles are active ingredients or additives and wherein said flexible robotic arm transfer racks from robotic arm to said comminution station.

4. The modular robotic system of claim 1,

5 wherein said rack holds up to six vials, wherein said rack is bar coded, wherein each said vial is bar coded;

wherein said materials is selected from the group consisting of vials, pipette tips, active ingredients, and additives; and

wherein said dispensing, pipetting, or characterization station further comprises:

10 a waste station, wherein fluid can be pumped to waste; and

a tool head, wherein said tool head is fit with at least one item selected from the group of items consisting of: rack gripper, plate gripper, vial gripper, filter gripper, cap gripper, pipettor, and dispense needle.

5. A modular robotic system comprising:

15 a rack and vial storage system for storing racks and vials;

a consumables storage system for storing materials;

a robotic arm for transferring vials from a first location to a second location, or for transferring racks from a first location to a second location;

20 a dispensing, pipetting, or characterization station for dispensing active ingredients, water, or additives to vials,;

a solid dispensing station for dispensing solids by weight into vials, wherein said solids are active ingredients or additives;

25 a liquids, suspensions, gels, or meltables station for dispensing high viscosity fluids, gels, pastes, or meltables, wherein said high viscosity fluids, gels, pastes, or meltables are active ingredients or additives;

wherein said combination of said active ingredients, water, and additives from said dispensing, pipetting, or characterization station, said solid dispensing station, or said liquids, suspensions, gels, or meltables station yields a formulation;

a mixing station for mixing formulation to yield mixture; and

5 a phase stability station for phase analysis of said mixture;

a flexible robotic arm station, wherein said flexible robotic arm transfer racks from robotic arm to a third location upon said modular robotic system; and

a comminution station for grinding solid particles;

wherein said first location is:

10 rack and vial storage system;

dispensing, pipetting or characterization station;

mixing or homogenizing station;

phase stability station;

solid dispensing station;

15 liquids, suspensions, gels, or meltables station; or

comminutor station;

wherein said second location is:

rack and vial storage system;

dispensing, pipetting or characterization station;

20 mixing station;

phase stability station;

solid dispensing station;

liquids, suspensions, gels, or meltables station;

flexible arm station; or

25 comminutor station; and

wherein said third location is:

rack and vial storage system;

dispensing, pipetting or characterization station;

mixing station;

5 phase stability station;

solid dispensing station;

liquids, suspensions, gels, or meltables station; or

comminutor station.

6. The modular robotic system of claim 5,

10 wherein said rack holds up to six vials, wherein said rack is bar coded, wherein each said vial is bar coded;

wherein said materials is selected from the group consisting of vials, pipette tips, active ingredients, and additives; and

wherein said dispensing, pipetting, or characterization station further comprises:

15 a waste station, wherein fluid can be pumped to waste;

a tool head, wherein said tool head is fit with at least one item selected from the group of items consisting of: rack gripper, plate gripper, vial gripper, filter gripper, cap gripper, pipettor, and dispense needle; and

20 a deck; wherein said deck is mounted with at least one device selected from the group of devices consisting of: bar code reader, decapper, cap source, orbital shaker, tank mix testing unit, injection port, dilution port, filtration device, particle size detector, viscometry detector, wash station, bead collection, photography system, trash collection chute, and particle microscopy system.

7. The modular robotic system of claim 5,

25 wherein each said rack is identified by bar code; and

wherein said robotic arm reads said bar code.

8. The modular robotic system of claim 6,

wherein said liquids, suspensions, gels or meltables station further comprises:

a second tool head, wherein said second tool head is fit with at least one item selected from the group of items consisting of: rack gripper, plate gripper, vial gripper, gel
5 dispenser gripper, cap gripper, pipettor, and vacuum canula; and

a second deck; wherein said second deck is mounted with at least one device selected from the group of devices consisting of: movable gel dispenser, comminuting bead source, bar code reader, decapper, orbital shaker, heated block, mass balance, trash collection chute.

9. The modular robotic system of claim 8, further comprising:

10 a second dispensing, pipetting and characterization station, wherein said second dispensing, pipetting and characterization station further comprises a third deck and a third tool head, wherein said third tool head is fit with at least one item selected from the group of items consisting of: rack gripper, plate gripper, vial gripper, gel dispenser gripper, cap gripper, pipettor, and dispense needle; and wherein said third deck is mounted with at least one device
15 selected from the group of devices consisting of: bar code reader, capper, decapper, caps source, balance, injection port, drain wash station, gel dispenser, orbital shaker, and heated block.

10. The modular robotic system of claim 9, further comprising:

an off deck, wherein said off deck is mounted with at least one device selected from the list of devices consisting of: second particle size detector, flush system, second viscometer, and
20 second particle microscopy system.

11. A method of preparing and characterizing formulations in a high throughput mode comprising:

loading rack(s) and vial(s), wherein said racks and vials are loaded into a rack and vial storage system;

25 loading consumables, wherein said consumables are loaded into a consumables storage system;

loading active ingredients, wherein said active ingredients are loaded on a liquid dispensing, pipetting, characterization station;

loading additive one, wherein said additive one is loaded on a liquid, suspensions, gels, and meltables dispensing station;

loading additive two, wherein additive two is a high viscosity liquid, and wherein said additive two is loaded in a gel dispenser;

5 loading additive three, wherein additive three is a solid, and wherein said additive three is loaded into a solid source hopper;

loading water, wherein said water is loaded on a liquid dispensing, pipetting, characterization station; and

10 transferring said consumables, wherein said consumables are transferred from said consumables storage system by a robotic arm and transferred on a rail to said liquids, suspensions, gels and meltables station and to said dispensing, pipetting, characterization station.

12. The method of preparing and characterizing formulations in a high throughput mode of claim 11, wherein said active ingredient is loaded through at least one bottle and wherein said bottle is connected to a valve and pump system.

15 13. The method of preparing and characterizing formulations in a high throughput mode of claim 11, further comprising:

20 transferring vial(s) from said rack(s) by said robotic arm, wherein said rack is located on said an entry point of said liquids, suspensions, gels and meltables station, and wherein said rack is moved to a dispensing location on said liquids, suspensions, gels and meltables station, and wherein said rack is moved by means of a liquids, suspensions, gels and meltables station tool head;

adding said additive one to said vial(s);

adding said additive two to said vial(s);

adding said additive three to said vial(s);

25 adding said active ingredient to said vial(s);

adding said water to said vial(s);

mixing said additive one, said additive two, said additive three, said active ingredient, and said water, within said vial(s) to form a formulation;

heating said formulation within said vial(s);

adjusting pH of said formulation within said vial(s) to from pH adjusted formulation;

5 mixing said adjusted formulation within said vial(s) to form mixed, adjusted formulation;
and

analyzing phase of said mixed adjusted formulation, wherein mixed adjusted formulation phase is analyzed with a turbidity analysis instrument to yield analysis results.

14. The method of preparing and characterizing formulations in a high throughput
10 mode of claim 13, further comprising:

analyzing analysis results, wherein at least one analysis result is transparent vial(s), and at least one analysis result is not transparent vial(s);

flagging each said vial(s), wherein an analysis result of transparent results in a passed flag, and an analysis result that is not transparent results in a reject flag;

15 disposing said not transparent vial(s);
storing said transparent vial(s).

15. The method of preparing and characterizing formulations in a high throughput mode of claim 14, further comprising:

20 re-analyzing phase of said mixed adjusted formulation within said stored transparent vials, wherein said re-analyzing occurs at least twenty-four hours after said analyzing phase;

wherein said mixed adjusted formulation is analyzed with a turbidity analysis instrument to yield analysis results wherein at least one analysis result is transparent vial(s), and at least one analysis result is not transparent vial(s);

25 flagging each said vial(s), wherein an analysis result of transparent results in a passed flag, and an analysis result that is not transparent results in a reject flag;

disposing said not transparent vial(s);

storing said transparent vial(s).

16. The method of preparing and characterizing formulations in a high throughput mode of claim 11, further comprising:

transferring vial(s) from said rack(s) by said robotic arm, wherein said rack is located on said an entry point of said liquids, suspensions, gels and meltables station, and wherein said rack
5 is moved to a dispensing location on said liquids, suspensions, gels and meltables station, and wherein said rack is moved by means of a liquids, suspensions, gels and meltables station tool head;

adding said additive one to said vial(s);

adding said additive two to said vial(s);

10 adding said active ingredient to said vial(s);

adding said water to said vial(s);

adding beads to said vial(s);

comminuting said additive one, said additive two, said active ingredient, and said beads, within said vial(s) to form a suspension;

15 aspirating said suspension, and dispensing said suspension into new vial(s);

measuring particle size distribution of said suspension, wherein said measuring is by way of a particle analyzer, and wherein said particle analyzer generates a particle size distribution profile;

20 comparing said particle size distribution profile of said suspension with a desired profile, to yield analysis results of pass or fail.

17. The method of preparing and characterizing formulations in a high throughput mode of claim 16, wherein comparison of said particle size distribution of said suspension with said desired profile yields an analysis result of pass, further comprising:

25 determining viscosity of said suspension, wherein a first viscometer detector determines high shear measurement, and a second viscosity detector determines low shear measurement;

comparing high shear and low shear viscosity with desired value(s) to yield analysis results of pass or fail.

18. The method of preparing and characterizing formulations in a high throughput mode of claim 17, wherein comparison of said high shear and low shear viscosity of said suspension with said desired value(s) yields an analysis result of pass, further comprising:
storing said suspension.

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